K110610

APR - 1 2011

GE Healthcare

510(k) Premarket Notification Submission

Section 5: 510(k) Summary

GE 6-Channel Phased Array Flex Coil

K110610

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510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date: March 1, 2011

Submitter: GE Healthcare (GE Medical Systems, LLC)
3200 N. Grandview Blvd.
Waukesha, WI 53188 USA

FDA Registration Number: 2183553

Primary Contact Person: Michelle Scheidt, Regulatory Affairs Leader
GE Healthcare (GE Medical Systems, LLC)
3200 N. Grandview Blvd., Mail Code: W-827
Waukesha, WI 53188
Phone: 262-521-6102
Fax: 414-918-8349

Secondary Contact Person: Glen Sabin, Regulatory Affairs Director
GE Healthcare (GE Medical Systems, LLC)
3200 N. Grandview Blvd., Mail Code: W-827
Waukesha, WI 53188
Phone: 262-320-6848
Fax: 414-918-8349

Device: Trade Name: GE 1.5T 6-Channel Phased Array Flex Coil and GE 3.0T 6-Channel Phased Array Flex Coil

Common/Usual Name: Coil, Magnetic Resonance, Specialty

Classification Names: 21 CFR 892.1000, Magnetic resonance diagnostic device

Product Code: 90MOS

Predicate Device(s): K042844, GE Signa Excite 1.5T 6 Channel Phased Array Flex Coil and GE Signa Excite 3.0T 6 Channel Phased Array Flex Coil

Device Description: The GE 6-Channel Phased Array Flex Coil is a surface coil used for Magnetic Resonance Imaging. It is tuned to image proton nuclei in a receive-only configuration. It is comprised of 6 individual phased array coil elements, each utilizing an integrated preamplifier to improve image quality. This coil is a receive-only, multi-coil array optimized for high-resolution examinations. The coil enables multi-oblique slice imaging. The coil is indicated for use, on the order of a physician in conjunction with an MR scanner, as an accessory to produce 2D and 3D images. The intended areas of interest to be scanned with the GE 6-Channel Phased Array Flex Coil include, but are not limited to: head, neck, knee, shoulder, foot, wrist, and hip. The 1.5T GE 6-Channel Phased Array Flex Coil is compatible with the Discovery MR450 (K083147) and the Optima MR450w (K091536). The 3.0T GE 6-Channel Phased Array Flex Coil is compatible with the Signa MR750 3T, now marketed as Discovery MR750 (K081028).

Indications For Use: The 1.5T GE 6-Channel Phased Array Flex Coil is indicated for use on the order of the physician in conjunction with a 1.5T MRI scanner, as an accessory to produce 2D and 3D images.

The 3.0T GE 6-Channel Phased Array Flex Coil is indicated for use on the order of the physician in conjunction with a 3.0T MRI scanner, as an accessory to produce 2D and 3D images.

Technology: The GE 6-Channel Phased Array Flex Coil is a 6-element phased array RF receive-only coil with integrated preamplifiers. The coil design consists of RF chokes with switching diodes to provide decoupling to isolate the coil elements from RF fields during RF transmission. The device modification present in this GE 6-Channel Phased Array Flex Coil compared to the predicate device, GE Signa Excite 1.5T 6 Channel Phased Array Flex Coil and GE Signa Excite 3.0T 6 Channel Phased Array Flex Coil

(K042844) is the changed electrical components in the connector. The preamplifiers are now located in the connector for the coil (Quick Disconnect box), rather than in the Low Profile Carriage Assembly of the MR System. This enables the coil to be compatible with the Discovery MR450 (K083147), Optima MR450w (K091536), and Signa MR750 3T, now marketed as Discovery MR750, (K081028) Systems, rather than the GE 1.5T and 3.0T Signa HDx MR Systems (K052293). Overall, the GE 6-Channel Phased Array Flex Coil employs the same fundamental scientific technology as its predicate device.

Determination of Substantial Equivalence:

Summary of Non-Clinical Tests:

The GE 6-Channel Phased Array Flex Coil and its applications comply with voluntary standards as detailed in Section 9, 11 and 17 of this premarket submission. The following quality assurance measures were applied to the development of the system:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Testing on unit level (Module verification)
- Integration testing (System verification)
- Performance testing (Verification)
- Safety testing (Verification)
- Simulated use testing (Validation)

Summary of Clinical Tests:

The subject of this premarket submission, GE 6-Channel Phased Array Flex Coil, did not require clinical studies to support substantial equivalence. However, clinical images from validation have been included in DICOM format in Section 20 of the submission.

Conclusion: GE Healthcare considers the GE 6-Channel Phased Array Flex Coil to be as safe, as effective, and performance is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Ms. Michelle Scheidt
Regulatory Affairs Leader
GE Medical Systems, LLC
3200 N. Grandview Blvd.
WAUKESHA WI 53188

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Re: K110610
Trade/Device Name: 1.5T GE 6-Channel Phased Array Flex Coil and 3.0T GE 6-Channel Phased Array Flex Coil
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: MOS
Dated: March 1, 2011
Received: March 3, 2011

Dear Ms. Scheidt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

K110610

510(k) Number (if known):

Device Name: 1.5T GE 6-Channel Phased Array Flex Coil and 3.0T GE 6-Channel Phased Array Flex Coil

Indications for Use:

The 1.5T GE 6-Channel Phased Array Flex Coil is indicated for use on the order of the physician in conjunction with a 1.5T MRI scanner, as an accessory to produce 2D and 3D images.

The 3.0T GE 6-Channel Phased Array Flex Coil is indicated for use on the order of the physician in conjunction with a 3.0T MRI scanner, as an accessory to produce 2D and 3D images.

Prescription Use_X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use_ _ (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Mary S Patel

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K110610